

### **REMARKS/ARGUMENTS**

The above-identified patent application has been reviewed in light of the Examiner's Office Action having a mailing date of March 5, 2008. Also filed herewith is a Request for Continued Examination and a request for a three-month extension of time and requisite fees associated with such requests. The following comprises the Applicant's reply.

In the above-referenced Office Action, the Examiner rejected pending Claims 1, 3-7, 9-13 and 15-21 under 35 U.S.C. § 103(a) as being unpatentable over Ortiz et al. ("Ortiz"; WO 02/03892).

#### **Finality of the Present Action**

"Under present practice, second or any subsequent actions on the merits shall be final, except whether the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims or based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. § 1.97(c) with the fee set forth in 37 C.F.R. § 1.17(p)." See MPEP § 706.07(a)(emphasis added).

First, it is noted that the rejections set forth in the instant Office Action were not necessitated by an information disclosure statement submitted by Applicant. Second, in the instant Office Action, the Examiner noted that "Applicant's amendment necessitated the new grounds(s) of rejection presented in this Office action." In the Office Action, the Examiner cites Ortiz, a reference which has been previously cited by the Examiner. Since the amendments did not necessitate a new reference, the Office Action should not have been made final. The Applicant, therefore, respectfully requests that the finality of the Office Action be withdrawn.

**Rejection of Claims 1, 3-7, 9-13 and 15-21 under 35 U.S.C. § 103(a)**

The Examiner has rejected Claims 1, 3-7, 9-13 and 15-21 under 35 U.S.C. §103(a) as being unpatentable over Ortiz et al. (“Ortiz”; WO 02/03892).

The U.S. Supreme Court, in KSR Int’l. Co. v. Teleflex Inc., 82 USPQ 2d 1385, 1391 (2007), reiterated the standard for determining obviousness under 35 U.S.C. § 103 as being the factual inquiries set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). In Graham, the Court stated that obviousness is determined by first determining the scope and content of the prior art, then ascertaining the differences between the invention, as claimed, and the prior art, and then resolving the level of ordinary skill in the prior art. Against this background, the obviousness or non-obviousness of the claimed subject matter is determined. Secondary considerations may also be utilized in this analysis to give light to the circumstances surrounding the origin of the subject matter sought to be patented. KSR Int’l Co., 82 USPQ 2d at 1391. When making any obviousness rejection, the Examiner must first acquire a thorough understanding of the claimed invention by reading the specification and claims to understand what the Applicant is claiming as his invention. MPEP § 904.

To establish a prima facie case of obviousness under 35 U.S.C. §103(a), the Examiner must clearly articulate the reason(s) why the claimed invention would have been obvious (i.e., the analysis supporting the rejection must be made explicit.) See MPEP § 2142. “Rejections on obviousness cannot be sustained with mere conclusory statement; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” See MPEP § 2142; In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006); see also KSR Int’l Co., 82 USPQ 2d at 1396. To support a 103(a) rejection, the examiner must demonstrate that a person of ordinary skill in the art would have had reason to

attempt to make the claimed device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. See Noelle v. Lederman, 355 F.3d 1343, 1351–52 (Fed. Cir. 2004); Brown & Williamson Tobacco Co. v. Philip Morris, Inc., 229 F.3d 1120, 1121 (Fed. Cir. 2000); see also KSR Int’l Co., 82 USPQ2d at 1391.

The restoring apparatus of the present invention intends to uniformly stabilize not only the diameter of the aortic annulus but also the diameter of the sinotubular junctions. Prior to the present invention, no attempts have been made to restore both the function of aortic root and aortic valve. Ortiz shows an apparatus for stabilizing the atrioventricular valve. As the Examiner may appreciate, heart valves are categorized into a total of four types of valves, namely atrioventricular valves (i.e., a mitral valve and a tricuspid valve) and vascular valves (i.e., an aortic valve and a pulmonary valve). The atrioventricular valve is opened and closed by pressure difference, whereas the vascular valve is opened and closed by twisting the blood vessels. The atrioventricular valve, which is the object of stabilization in Ortiz, and the vascular valve, which is the object of stabilization in the present invention, have completely different structures and gating mechanisms.

Accordingly, the structure of the restoring apparatus is different from that according to Ortiz. The present invention comprises two independent repair apparatuses (i.e., the aortic annulus and the sinotubular junction) whereas the apparatus according to Ortiz is directed to an upper part and bottom part incorporated as a single apparatus, therefore having a interdependency of the upper and bottom part. Therefore, in order to preserve the function of twisting, tilting and elasticity, the independency between the aortic annulus and the sinotubular junction is essential. Since these apparatuses are applied to blood vessels, the structure must be “ring” or “band” type. Further, since the apparatus according to Ortiz fixes the entire

circumference of the heart annulus, the necessity and the possibility of selectively fixing part of the heart annulus, i.e., the fibrous part and the muscular part, cannot be achieved.

The repair apparatus of Ortiz is a ring-type, whereas the sinotubular junction repairing junction apparatus of the present invention is a ring-type but the aortic annulus repairing apparatus is a band type. Therefore, Ortiz is not identical with the restoring apparatus according to the present invention. Since the aortic annulus repairing apparatus is constructed as a band-type it may selectively fix only the fibrous portion of the aortic annulus. The aortic repairing apparatus of a band type according to the present invention stabilizes the fibrous layer, exclusive of the muscular part, at the aortic annulus. The muscular layer is the part in which the heart moves, and a cardiac conduction system passes through the inside thereof. If the muscular layers are fixed, this may block the smooth functioning of the heart, thus, it is preferable to fix only the fibrous layer.

The repair apparatus of Ortiz is applied to the atrioventricular valve and stabilizes the upper and the lower part of the valve in the blood vessel, while in the present invention the repair apparatus is applied to the vascular valve and stabilizes the inside and outside of the blood vessel.

Because of the foregoing arguments, the present invention is not obvious in the light of the disclosure of Ortiz. Applicant believes he has sufficiently traversed the currently asserted rejections set forth by the Examiner in the March 5, 2008 Office Action, and therefore respectfully requests withdrawal of the Examiner's rejections.

**CONCLUSION**

Based upon the foregoing, Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Dated this 3rd day of September, 2008.

Respectfully submitted,  
/Paul S. Cha/  
**Paul S. Cha**  
Registration No. 54,022  
Attorney for Applicant  
Holme Roberts & Owen LLP  
Customer No. 23337  
Telephone: (303) 861-7000